UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF OKLAHOMA

IN RE: GENENTECH HERCEPTIN (TRASTUZUMAB) MARKETING AND SALES PRACTICES LITIGATION.	)))	Case No. 16-MD-2700-TCK-TLW ALL CASES

REDACTED TRANSCRIPT OF RECORDED PROCEEDINGS
NOVEMBER 17, 2016
BEFORE THE HONORABLE T. LANE WILSON, MAGISTRATE JUDGE PRESIDING

MOTION HEARING

Greg Bloxom, RMR, CRR
United States Court Reporter
Northern District of Oklahoma

A P P E A R A N C E S

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PROCEEDINGS:

THE DEPUTY COURT CLERK: This is case number 16-MD-2700-TCK-TLW, Genentech Herceptin Marketing and Sales Practices Litigation.

Counsel, please enter your appearance for the record.

MR. KEGLOVITS: On behalf of plaintiffs, Dave Keglovits, Steve Adams, Matt Sill, Wes Pebsworth and Amy Fogleman, and I think Katie Griffin is on the phone.

MR. O'CONNOR: On behalf of Genentech, Bill O'Connor, Alicia Donahue and Gabe Egli.

THE COURT: Let's talk about this ESI order first. I think, in general, it looks like it's well thought out and I don't have the any concerns about it. I have a few questions and I guess I've got one potential concern.

In terms of the searches that are contemplated, are you all simply talking about agreeing on a list of words and then the database will then be searched for documents that contain those words on them, or are you contemplating a situation that's more sophisticated where you might pull some documents that are clearly relevant and then utilize a third-party vendor to use some algorithmic functions that would then provide, you know, a better set of relevant documents?

MR. EGLI: I think the former, Your Honor, talking about running word search terms --

THE COURT: Okay.

MR. EGLI: -- on the database.

THE COURT: And I'm just curious. I mean, why would you -- I mean, there's been a lot of research into this area and it tends to show that that method is slightly better than putting an eyeball on every document, but just barely slightly better, and that oftentimes putting an eyeball on every document and simply using search terms is -- I don't want to be too extreme in this, but I think the research shows this can be grossly ineffective, and so why would you do it that way?

The problem with those, as well, is that you tend to end up with thousands if not millions of documents that aren't real helpful to the case. So, I mean, what's the thinking there? Why wouldn't you utilize the current state of technology and try to get a smaller set of more relevant documents?

MR. EGLI: Your Honor, I think the search terms, if used properly with some quality control can actually be pretty reliable. The TAR methodology I think that you're talking about, the Technology Assisted Review, there are additional cost considerations there.

If you're dealing with a larger volume, it tends to make more sense, but setting it up and getting those things running mean a lot more in terms of costs on the front end.

THE COURT: Well, maybe I misunderstood. I mean, my impression is that if we go forward with some of this

discovery, we're talking about a very large number of documents to be searched. But what you're saying is that it's just not that large?

MR. EGLI: We don't, I think, know, probably, Your Honor, at this point how large that's going to be. But, you know, I think we've seen, in addition to using things like TAR, sometimes search terms, they'll get used to feed those documents in as well. So I think that, you know, we started with the search terms just because that was something that both sides felt comfortable with had used before effectively, and there would probably be fewer negotiation points along the way if all we're talking about is generating those terms as opposed to figuring out how exactly we're going to be feeding documents into a Technology Assisted Review system.

THE COURT: Okay. All right. Well, you know, in the end, it is -- anything from the plaintiffs in that regard?

MR. KEGLOVITS: I'll only confess ignorance. I had not thought this was going to come up. Mr. Doverspike is the one who's been handling that on our end, so I may not understand everything that we're talking about. I know there are particular documents that we believe we should get, and we've given them a list of those. I don't think what we're talking about, but again I'm going to confess my ignorance, is going to replace that kind of searching. If it is intended to replace the kind of searching, then I would go back to the

first question and say I want to do more than just search terms against a database.

THE COURT: Okay. Well, I'll sign the order. I mean, my interest in this is one of efficiency and the concern, you know, like most people have, is that federal court litigation has just become too expensive, particularly in these large cases. And my understanding of the Technology Assisted Review is that you do oftentimes begin with a couple of search term searches and then the goal being to find documents that one side or both agree actually are relevant as opposed to, you know, somebody's name appearing on a document 1,500 times on an issue that has nothing to do with the case and then using those documents to then generate searches that will pull more similar documents as opposed to the documents that aren't relevant.

But, you know, if you all want to -- I mean, you seem to be in agreement because you presented the order. You know, I don't mean to be critical, I'm certainly not trying to do that. I was just curious because it appeared to me as though it was going to be a search term effort as opposed to a TAR effort. So, if the parties are okay with the order, then I'll go ahead and sign it.

MR. EGLI: Yeah. Your Honor, if I could say one more thing. If it turns out that we're dealing with a large volume, we may revisit that, and I think the protocol actually contemplates revisiting if we needed to to amend an order for

TAR, although the parties may just agree to do that --

THE COURT: Okay.

MR. EGLI: -- in that event.

THE COURT: And that would be fine. You know, one of the things I'm trying to break through, and I'm beginning to, you know, be a bit older and so maybe I fall into this category, but, you know, the idea that, you know, putting an eyeball on every document or doing these old traditional searches is actually an effective way of finding relevant information I think has pretty well been dispelled. And at least it doesn't sound like you all are planning on doing that, looking at every document that might be relevant. So I'll sign the order, and if you all have any issues, then just raise it with Camie and we'll get everybody back in here and we'll get them resolved.

Okay. Camie is letting me know. Yeah, Mr. Keglovits, can you pull that mic up? And so I'm not going to have you all come to the podium. This is going to be more a discussion than anything else, so if you want to, you can certainly remain at the table. Just when you're speaking, make sure you're speaking into the microphone so that we get everything taken down.

All right. Let's move on to the discovery disputes in this joint submission that you all made. I assume there are no updates since then. Any progress has been made, no progress?

All right. I see shaking heads no, so then we'll move forward.

All right. I've read the summary judgment motion a couple of times, and if I understand it correctly, I mean, there's essentially two arguments in that summary judgment motion, and one is that plaintiffs' claims directly conflict with federal net weight standards and, thus, would stand as an obstacle to the purpose and objectives of Congress and the FDA in allowing for variations in that content. I mean, this is essentially, you know, the obstacle preemption argument.

And then the second one, the impossibility, is that it would be impossible for Genentech to comply with its federal law obligations which prohibit it from modifying its manufacturing process and net weight specifications which it would have to do in order to comply with the state law upon which plaintiffs' claims are based.

On the first one -- well, and then let me go ahead and say, in reviewing the motions and the joint submission, my understanding of plaintiffs' discovery requests is that they essentially involve two areas, and one is -- one was initially stated as the availability of labeling changes including discovery of information putting Genentech on notice of the fact that such changes were necessary. And then, two, really the manufacturing processes that would require modification.

I mean, have I, in a very general sense, captured the summary judgment motion and then sort of the areas of discovery

that plaintiff is seeking?

MR. KEGLOVITS: From the plaintiff's perspective, Your Honor, yes.

THE COURT: Okay. All right. How about from the defendants' perspective?

MS. DONAHUE: Yes, you've captured the motion -- the essence of the motion.

THE COURT: All right. Then am I right that the labeling issue relates primarily to the first point on the summary judgment motion?

MS. DONAHUE: From a defense perspective, yes, Your Honor.

THE COURT: Okay. Mr. Keglovits, is that the same?

MR. KEGLOVITS: I think primarily, but I think there is an element of obstacle in what we're trying to learn about particularly communications to and from the FDA to ascertain the FDA's actual stated position on some of the things from which we get a declaration -- or on which we get a declaration from their expert.

THE COURT: Okay.

MR. KEGLOVITS: But I do think primarily it's impossibility.

THE COURT: Okay. But the labeling issue, the issue of labeling is related to, as I understand it, the obstacle preemption argument, and the manufacturing issue is related

primarily to the impossibility. Have I got that right?

MR. KEGLOVITS: Well, I think impossibility sweeps up both manufacturing and labeling. For instance, on obstacle, they have an expert who is opining that Herceptin is a solid drug. That's the linchpin to their obstacle preemption argument. So, if there are communications back and forth with the FDA about whether the FDA's position is that this is a solid drug, then I think that would be discoverable.

THE COURT: Okay. Right. Right now I'm just talking about in terms of the labeling issue, do you think the labeling -- the discovery you seek on the labeling, do you think it goes to both the obstacle and the impossibility?

MR. KEGLOVITS: No, I -- yes, I think, if I'm understanding the question.

THE COURT: Okay. So help me understand how discovery as to the label relates to the impossibility preemption defense.

MR. KEGLOVITS: Well, the FDA is obviously involved in the labeling process, and so coming back to the fundamental question of communications with the FDA on things like whether it's a liquid or a solid drug, or whether the FDA, in approving a particular aspect of the label, took into account another aspect of the CMC.

THE COURT: Okay. But my understanding of Genentech's argument on impossibility is that the reason the impossibility

defense is applicable is because in order to comply with Oklahoma State law they would have to change their manufacturing process which would then put them outside the FDA regulations with respect to Genentech.

I mean, Ms. Donahue, do I misunderstand that?

MS. DONAHUE: Our impossibility defense is based on the fact that in order to comply or reach what the plaintiffs would like us to reach in terms of the vial fill amount, we would have to get FDA approval to change our manufacturing --

THE COURT: Process?

MS. DONAHUE: -- process.

THE COURT: Right, right.

MS. DONAHUE: And what "impossibility preemption" means is that if, in order to comply with the state law claim or state law requirement, one would have to seek FDA approval, then that is preempted.

THE COURT: Okay. Right. But --

MS. DONAHUE: It's not whether you can do both. It's whether, even to do both, you would have to get FDA approval to do what the plaintiffs are saying --

THE COURT: Yeah. And let --

MS. DONAHUE: -- you've got to do.

THE COURT: I want to set the legal issue -- the argument over the legal issue aside. I mean, the factual basis of your impossibility defense is we would have to change the

manufacturing process.

MS. DONAHUE: And in order to do that, we would have to get FDA approval.

THE COURT: And we would have to get FDA approval.

MS. DONAHUE: Yes.

THE COURT: Okay. So, if that's the factual basis of Genentech's motion for summary judgment on the impossibility defense, how does labeling relate to that? I mean, because right now all we're doing is talking about how do we make sure that the plaintiffs are well situated to respond to the summary judgment motion.

MR. KEGLOVITS: Well, I guess I didn't understand their argument to be that narrow. And perhaps what they will do is stipulate that they could have independently changed the label to say the net weight is XXXXXXXXXXXXXXXXXXX or the concentration is a number different than 21 milligrams per milliliter, but I don't hear them saying that.

THE COURT: Okay. Well, again, I mean, the labeling issue -- and, Ms. Donahue, maybe you and I need to flush this out a little bit -- the labeling issue, it seems to me, goes to the obstacle preemption --

MS. DONAHUE: Correct, Your Honor, --

THE COURT: -- defense --

MS. DONAHUE: -- yes, the obstacle preemption.

THE COURT: -- and not to the impossibility defense.

That the impossibility defense is simply, "We can't do this because we would have to change our manufacturing process which would require us to go to the FDA and seek approval and, therefore, we can't comply, it's impossible for us to comply with both sets of laws."

And so if that's their -- I mean, I hear -- I think I heard Ms. Donahue say this, I don't know that we necessarily need a stipulation, but I think what she is saying is, and this is certainly how I read the summary judgment motion, is, "The factual basis of our impossibility defense is simply that we would have to change the manufacturing process in a way that would require us to get FDA approval." Am I right, Ms. Donahue?

MS. DONAHUE: Yes.

THE COURT: Okay. So, it's not that -- they're not saying that we would have to change the label. They're not saying -- I mean, they're saying that on the -- they're addressing the label on the obstacle preemption issue, but on the impossibility, if Ms. Donahue is saying that right now, "Look, this is the factual basis of our claim, of our defense," then on the impossibility defense -- and we'll get to obstacle in a minute -- but on the impossibility defense, I'm trying to figure out why we should be talking about any discovery that's not related to the manufacturing process.

MR. KEGLOVITS: Well, ultimately, I think the label is

implicated in one or both of the defenses that have been raised. And certainly we can respond to the impossibility defense by saying, "Let's assume you're right, that you don't have to change the manufacturing, but it is possible to change the label, and you can then do, independent of the FDA, what needs to be done to comply with both federal and state law, and therefore it is not impossible."

THE COURT: Okay. But that's a legal issue. I mean, that's a question for the court to determine, whether or not they can -- whether or not they can do that. I mean, setting aside the manufacturing process, whether or not they can seek a change in the label or comply with both sets of laws, that's a legal issue. The factual issue is the manufacturing process.

MR. KEGLOVITS: I respectfully disagree that it's a pure legal issue, and that's, of course, why they have a declaration on the labeling issues. And certainly if you look at the regulations, there are exceptions that clearly allow a manufacturer, if a certain factual predicate is met, to independently change the label. For example, the newly acquired information test. So, we would have to develop a factual record to support that they would qualify under that exception to independently change the label.

MS. DONAHUE: Your Honor, those points just there are, in fact, issues of law. This doesn't -- and the declaration that we've submitted in support of our obstacle preemption

defense is by an FDA regulatory expert who is simply setting forth for the court what the regs are that apply in this case. It's a legal issue. We don't fall within the exceptions that they continue to point to. There was no newly acquired information because the FDA knew at the time of approval that there this was this spec range and that we were required -- and it was labeled with the knowledge of the spec range. The FDA approved the label, approved the manufacturing process, approved the drug with the spec, and has had -- and it has been the same ever since. The FDA's knowledge nor Genentech's knowledge didn't change over time. That's the reality of the situation since 1998.

So, in terms of obstacle preemption, it's based on the reg, it's based on the approval letter from the FDA where they say to us, "If you want to change your label, you need to come back and propose it and get approval pursuant to your BLA," and we have that letter. So, I mean, it is a legal issue. The first part of our motion is a purely legal issue.

MR. KEGLOVITS: The idea that their state of knowledge has never changed or the FDA's state of knowledge has never changed or the FDA has never recommended a change is a factual question.

THE COURT: If -- okay. Let's just follow this for a minute, this line of reasoning. If you were to obtain discovery that indicated that there was some newly acquired

information that -- that what, that they could manufacture it within the current FDA specs and make sure they had 400 milligrams in every vial? I mean, is that the sort of information you're looking for?

MR. KEGLOVITS: Well, I guess --

THE COURT: I mean, what --

MR. KEGLOVITS: -- two points. On the labeling, purely, and not manufacturing, we attached to the joint submission as exhibit 1 the meeting notes from the October, 2014, meeting between the FDA and Genentech. XXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX This is happening in 2014. So --

THE COURT: Okay. So relate that to the impossibility defense. Because if the label's revised, then --

MR. KEGLOVITS: Here's how I see it relates. XXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

THE COURT: Okay. So how does that relate to the impossibility defense?

MR. KEGLOVITS: Well, impossibility is bound up in the idea that you cannot independently do what we say needed to be done to comply with state law. And what this reg says is you

can change your label to provide the accurate information about what your manufacturing process generates, you can do that independently, and therefore you could have complied with both federal and state law. So it's not impossible to comply with both.

THE COURT: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

MR. KEGLOVITS: Well, that's in the regulations, and the regulations say, for this kind of change, that you can do it with a CBE, you can independent do it as long as you submit a changes-being-effected notice to the FDA. You don't have to get preapproval to do that.

THE COURT: And you're saying that situation occurs under what factual scenario?

MR. KEGLOVITS: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

THE COURT: Okay. So you've got that document. So you're looking for, what, other documents --

MR. KEGLOVITS: Sure.

THE COURT: -- that would indicate that the FDA had said this before?

MR. KEGLOVITS: Because I'm going to guess that Genentech isn't going to stipulate today that that note in that document is sufficient to trigger the exception in the reg that we've identified. So we need to know the entire discourse between the FDA and Genentech about --

THE COURT: Well, you don't need the entire discourse. XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

MR. KEGLOVITS: Yeah, ultimately that's where we want to go, but I don't think the volume of communication between the FDA and Genentech has been demonstrated to this point to be so high that we couldn't look at it all and not be forced to rely on someone else's filter to tell us what we need and what we don't need.

You know, just as a point here, so far in production we have nine faxes to the FDA and six e-mails from Genentech to the FDA. We have zero Genentech internal e-mails, zero customer or third-party inquiries which could give rise to newly acquired information, zero the manufacturing agreements, zero the manufacturing standards and instructions, zero the quality controls and audits. And so we're not sitting on top

of a mountain of information right now. All we're asking is that they go back with respect to this issue and provide us the catalog of what has gone back and forth with them and the FDA.

MS. DONAHUE: So, Your Honor, if we could just focus on the labeling issue for a minute --

THE COURT: Yeah, go ahead.

MS. DONAHUE: -- and address two points, I think, that are important to remember in response to Mr. Keglovits. And Mr. O'Connor is going to talk about the 2014 submission. But in terms of XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXX a changes-being-effected process versus seeking FDA approval, we have produced to the plaintiffs over 60 changes-being-effected submissions that we sent to the FDA on Herceptin. Okay? Of those, eight were label related. And because CBEs are appropriate in cases where there are safety issues, which makes sense because the FDA wants safety issues to be addressed quickly and says to the companies, "Go ahead and make your change right away if you think there's a safety issue." And that's what the *Wyeth* case the plaintiffs keep pointing to relates to.

The reg is clear that in a case such as ours where we're talking about quantity, quality content of a drug or biologic, a, you know, submission requesting approval is the only way that a company is allowed to change that portion of the label. It's what our approval letter from the FDA tells us and it's

what's the reg tells us.

So, any communications that we might have had about labeling changes, they know what our CB- -- they know every CBE we've submitted and we're about to give them any supplements to those. But, I mean, there's --

THE COURT: Okay. Let --

MS. DONAHUE: -- over 60 --

THE COURT: Let me --

MS. DONAHUE: -- and they don't relate to this issue.

THE COURT: Let me -- maybe I'm just being thick about this.

All right. What I'm being told is that the attorneys we have on the phone can hear me but they cannot hear you all. Maybe that's a good thing. So, as you all are speaking, then you're probably going to have to bring those mics closer to you. I mean, if you want to come to the podium, you can. That just is, to me, it disrupts things.

All right. Again, on this labeling issue, you know, I'm just -- and maybe I'm just missing something -- Genentech is saying, "We can't change the manufacturing process and there's no way we can manufacture the drug to be consistent with what Oklahoma law requires us to do." And one response I'm hearing from the plaintiff is, "But they could have changed the label without getting approval." But I don't hear Genentech saying, on the impossibility defense, "We couldn't have changed the

label." I hear them saying that on the obstacle preemption, but on the impossibility defense I don't hear them saying that, "We couldn't have changed the label." I only hear them saying, "We would have had to change our manufacturing process."

MS. DONAHUE: Because under obstacle preemption, where there is a federal regulation or law in effect, then that is obstacle preemption.

THE COURT: Okay.

MS. DONAHUE: Impossibility preemption is we would have to seek FDA approval but not necessarily under any specific regulation.

THE COURT: Okay. But what I understood your summary judgment motion to be arguing on impossibility preemption is not, "We have to change our label." You're not -- in other words, as Judge Kern looks at this or when the plaintiffs respond, your reply is not going to be on the impossibility defense, "But we couldn't change our label."

MS. DONAHUE: No, it's not.

THE COURT: So, why -- and, again, I'm only talking about the impossibility defense. So I understand, Mr. Keglovits, what's you're saying, but what you're saying seems to me, since they're not raising it at this stage of the litigation, it seems to me to go potentially to the ultimate merits, but not to a preemption defense on impossibility because they're not saying -- they're not taking the position

that they couldn't change the label on that defense, they're not using that as a reason to assert that defense. So why is -- and, again, I'm only talking about the impossibility defense -- so why is that discovery relevant to that defense?

MR. KEGLOVITS: Well, again, I think it's because it allows us to win. If we can show --

THE COURT: Win the case?

MR. KEGLOVITS: Well, yes, but win this issue. If we can convince Judge Kern you don't even have to look at manufacturing, and we can talk about it in a second because we haven't, there's a lot of facts there we want to talk about, but you don't have to look at manufacturing, forget about manufacturing because they could have solved this problem by changing the label.

THE COURT: But if you convince him, "Forget about manufacturing, there might be discovery out there that would render that issue moot," then don't you win the summary judgment issue, because they're not arguing that?

MR. KEGLOVITS: Right, but we want to develop the factual support for that argument so we can win it. And --

THE COURT: But --

MR. KEGLOVITS: -- I have to say I'm a little surprised that the correspondence between Genentech and the FDA about Herceptin, and particularly about the Herceptin label, is even something that they're resisting discovery on. This is

one of the things that extemporaneously I mentioned to Judge Kern when we first talked about doing this expedited summary judgment process as the discovery that we would need, and no one stood up and said, "Oh, wait a minute, that's not going to be necessary." Really, we're talking about the communications between this company and the regulator. It is not -- No one has established in any form or fashion that it would be burdensome to produce that to us. There's nothing that says it's a million pages or even a hundred pages. They're just saying, "We're right on the law and therefore we don't have to produce it."

THE COURT: All right. So, I want to stay to the point I'm talking about. So your position then is even if they're right, even if you were to concede that they would have to change their manufacturing process and that would require FDA approval, they still don't win on the impossibility defense because they could have changed the label without getting FDA approval. That's your position?

MR. KEGLOVITS: If you accept the premise that a change in manufacturing is simply a red herring, that the only thing that needed to be done was to change the label so that you could independently comply with federal and state law, then we win.

THE COURT: All right. Okay. So I think I understand the parties' positions now.

Now let's talk about -- I'll go ahead and address this issue. I mean, on the correspondence between the FDA and Genentech, I mean, what volume are we talking about? Is there -- I mean, how hard would it be to simply produce the correspondence? My understanding, I've read the law, and again I'm not an expert in this as you all are, but as I've read the law and that information used to be obtainable -- I guess it's not the correspondence -- but the way I read the law, that information, with the exception of anything that would be a trade secret, would be producible by the FDA under a FOIA request.

MS. DONAHUE: So, I'll let Gabe talk about the volume, but first off I just want to make sure that it's understood on the record that we have produced correspondence between the FDA and Genentech on the Herceptin labeling, and that is contained in the 15,000 pages of documents we've produced including the CMC of our BLA.

THE COURT: Yeah.

MS. DONAHUE: Every single CBE submission is correspondence with the FDA.

THE COURT: Right, but what --

MS. DONAHUE: And the 2014 dialogue that they have referred to, that also is correspondence with the FDA.

THE COURT: Okay. But in terms of, as Judge McCarthy would say, what do you have that you haven't produced? Just on

the correspondence issue, that's all I'm talking about. I'm not talking about any of the other requests. Just in terms of correspondence that the FDA has sent you on the labeling issue or you have sent the FDA.

MR. EGLI: Your Honor, we have a regulatory database that contains this. I don't know that there's a way to really separate out what's a submission, which I think would still qualify as correspondence with FDA versus, you know, an e-mail or a fax, for example.

THE COURT: But a submission would be formal enough that you would know whether it dealt with the labeling. I mean, I would imagine that your systems are sophisticated enough to cull out submissions that didn't relate to labeling.

MR. EGLI: I think that would be part of the process, Your Honor. The fact of the matter is the regulatory database contains all of the submissions and correspondence, and that's one of the things that we have, I think, concerns about here is that the request is for all communications regarding labeling regardless of whether they have anything to do with the content or concentration issues that are going on here, because a lot of those correspondence have to deal with -- have to do with clinical trials, for example, and --

THE COURT: Okay. Well, I mean, let's say that we limited it to what is going on here. How much are we talking about, and are your systems capable of culling that out?

MR. EGLI: I think if we could come to some search terms, it would probably be capable of that. One of the complicating aspects of it is a lot of these documents have cover sheets where you check boxes as to what it relates to. Without opening each of those, they're going to contain a label in that sheet, so it's not as simple as just using a label as a search --

THE COURT: You've got to look at the sheet to see if there's a check box, a label check box?

MR. EGLI: I suppose that that would apply to the submissions. The correspondence pieces, yeah, you might have to look more closely.

THE COURT: But the correspondence pieces, if you're using search terms, they are less likely to deal with -- to not deal with labeling if they have the word "labeling" in them?

MR. EGLI: Correct. Yeah. But if there's going to be, you know, a lot of what's contained in the regulatory database, which I think we've indicated at this point is well over four million pages, a lot of that stuff is going to be unrelated to labeling issues. I mean, as Ms. Donahue pointed out, we've produced over 60 CBEs, eight of those are labeling related, five of those are related to safety changes, and there are a couple of others that happened in 2000 where the labeling was changed to add things like nominal content is 440 and the concentration is approximately 21.

THE COURT: Well, Mr. Keglovits, what's the likelihood that a submission -- because the correspondence you're referring to obviously wasn't a submission by Genentech, it was just a letter from the FDA.

MR. KEGLOVITS: Well, it was a formal meeting between the FDA and Genentech which was memorialized in these minutes.

THE COURT: In the minutes. Okay. So, I mean, is there really, on this topic, any need for Genentech to search the submissions? I mean, aren't what you're really looking for is either minutes or letters or maybe e-mail that somehow addresses the labeling issue?

MR. KEGLOVITS: Not knowing what a submission is, it's kind of hard to answer. I mean, if the CEO of Genentech was sitting where you were and asked these folks, "Give me tomorrow all of the communications with the FDA on these issues," I guess the answer wouldn't be, "We've got a four-million page regulatory database that we really can't search so we can't do that." I've got to believe that there's somebody there who can untangle this knot and provide some organization to it for us, and maybe that's taking the deposition of a person who's in charge of their records system.

We know, from the documents they have produced, we know they've got commercial and launch teams for Genentech; we know they've got product investigative reports; we've got -- Genentech and Roche conduct product complaint investigations.

THE COURT: Okay. Well, let's just do this. I mean, the federal rules contemplate just a discussion. I don't think that we need a deposition of anybody from Genentech to address this issue. On the issue of the labeling and any correspondence, I want you all to get together and have a discussion with whoever it is at Genentech that knows the database or how records are kept. And I want both sides to keep in mind -- this really is directed towards the plaintiff -- that I am concerned about proportionality here and the costs involved.

By the same token, I mean, it does seem to me that obtaining most of what the plaintiffs are asking for in this regard shouldn't be that difficult. I mean, with a company like Genentech, I would tend to probably agree with what Mr. Keglovits is saying, is that there's got to be some way to obtain this correspondence as far as it relates to labeling. So I want you all to get together.

My understanding of the term "submission" is we're talking about some kind of formal document that maybe is required by the regs, maybe it was requested by the FDA, because my understanding from what Mr. Egli said is -- am I pronouncing that right?

MR. EGLI: You are.

THE COURT: Okay. -- what Mr. Egli said is that there's some form on the top of it and they check a box. I

mean, to me, that feels more formal than really, Mr. Keglovits, potentially what you're looking for. And so I want you all to talk about that.

I am going to allow discovery into correspondence between the FDA and Genentech on the issue of labeling, but I want it to be proportional. You know, whether it's search terms or whatever it is, I want you all to get together and talk about that because we're not going to search every document Genentech has for a needle that could be, you know, a potential e-mail that in the third paragraph talks about, you know, labeling, when the rest of the e-mail talks about something else. I mean, if you happen to find that document, fine, but I want you all to have an honest discussion about, you know, how you would obtain this information.

MR. EGLI: Just a question for clarification, Your Honor. Are we talking about labeling-related correspondence that deals with these content and concentration issues?

THE COURT: Is there any reason that you at this stage of the litigation would need anything else, Mr. Keglovits?

MR. KEGLOVITS: I don't think so.

THE COURT: Okay. Yes.

MR. EGLI: Thank you, Your Honor.

MR. KEGLOVITS: But also on clarification, I know Your Honor realizes that this is a putative nationwide class with hundreds of millions of dollars of damages, and this issue,

according to Genentech, makes it all go away. So it's hard for me to put that proportionality filter over an issue as important as this.

THE COURT: No, I understand that, but I also -- I understand your point, but simply because, you know, a case has got, you know, maybe a billion dollars at stake doesn't mean that we should throw out the idea of proportionality. I just don't think that's what the rules are asking us to do. And you've already got one document that you think indicates that their defense is not going to succeed. I know you're looking for more of those similar type documents, and you ought to be -- my view is you ought to be entitled to obtain those, but we're not going to spend, you know, $100,000 looking for that document. I mean, if it's there, you all ought to be able to come up with some search terms. We've limited the scope that are most likely to find this information.

And my view on discovery is always, you know, if you come up -- if you start coming up with e-mails, letters, minutes that address this issue time and again, well, then, I'll be willing to consider expanding the scope. But until then -- I mean, part of me wonders, you know, if you don't already have what you need, if Judge Kern agrees with your view legally and factually on this issue, then part of me says, "Well, you've already got what you need." I mean, he can look at those minutes. If Judge Kern says -- I mean, I guess in my reading

of this information, I don't see Judge Kern saying, "Well, I agree with you completely, Mr. Keglovits, but you only have one set of minutes. If you had 15, then you would prevail -- you would beat this summary judgment, but you've only got one." I don't see that happening.

MR. KEGLOVITS: Well, if I was confident that Judge Kern would say I would win based on this, I wouldn't ask you for this. It's the conundrum you're always in in discovery when you get a little bit from the defendant that opens the window into the world that you imagine has a lot more there. Oftentimes the court will say, "Well, don't you have enough," and until the end of the fight you don't know.

THE COURT: Yeah. Well, and that's what we're trying to do here. So I think --

MR. O'CONNOR: Your Honor, may I say something here?

THE COURT: Go ahead.

MR. O'CONNOR: One of the problems we're having is we haven't turned to Rule 56(d) or the Manual on Complex Litigation, both of which would require some specificity in the form of an affidavit from somebody beyond just conclusory assertions or advocacy from a lawyer. I mean, I've just listened patiently to what he's saying about a phone call that occurred with the FDA. A phone call occurred. That phone call was documented.

THE COURT: Right.

MR. O'CONNOR: There's no action since then. In fact, there's been action by the FDA that's completely contrary to this, and so we have an expert who was the division director from the FDA that --

THE COURT: Right. I understand that, Mr. O'Connor.

MR. O'CONNOR: So if there is an expert, --

THE COURT: Well, but --

MR. O'CONNOR: -- somebody that would say, "We need this to respond," because what I'm hearing over here is completely nonsense in the regulatory scheme and doesn't -- certainly doesn't counter what Dr. Lin, who is the expert on this issue, has professed, that it's proper to have 440, that that is properly labeled as meaning XXXXXXXXXXXXXXXXX that the manufacturing processes to change would require approval, that the label change would require FDA approval. But instead, I just hear a lawyer over here saying, "Hey, you can do this under this reg," without any approval --

THE COURT: Well, --

MR. O'CONNOR: -- and that's contrary to the very --

THE COURT: -- but Mr. O'Connor, I mean, he has a document that indicates under a -- and I'm not saying I agree with his argument -- but under at least a good faith argument that might assist him in avoiding your summary judgment motion. And I understand what you're saying, and we struggle with these issues all the time in these large cases, and, that is, you

know, how piecemeal do you pursue the litigation?

I mean, certainly, you know, I could require Mr. Keglovits to go out and obtain an expert that rebuts the things that your expert says and then lists all the factual material that expert would need, and then we could pursue discovery that way, but that's not typically how we do it, and I'm trying to reach, you know, a balance here between a very far-reaching search and one that hopefully will be designed to obtain the sort of information that I think Mr. Keglovits has laid out a good faith basis that it's actually relevant, and I think I have probably reached the right balance here because Mr. Keglovits is clearly unhappy with my decision, and Mr. O'Connor, you clearly are unhappy as well, so I'm probably right where I ought to be.

So you all --

MR. O'CONNOR: I just didn't want you to -- I didn't want you to make these decisions based on what counsel is advocating versus what's real, because what they -- I mean, I could go into a list of 10 things they haven't shared with you. They haven't shared that Genentech proposed some language to the FDA. They haven't shared that the FDA hasn't done anything, has taken no action in two years. They didn't share even any part of Genentech's detailed response. They didn't share that the guidance itself says that this is just suggested or recommended, it's not required. They didn't share in the

very letter approving the drug that the FDA says, "Any changes in the manufacture, packaging or labeling of the product or in the manufacturing facilities will require the submission of information to your biologic's license application for our review and written approval consistent with 21 CFR 601.12."

So, I just don't want to start going down a path here where we think it's -- you know, they've said in their papers, one, that this issue is fatal to our preemption defense. They've said that they have many -- in another part of their response they say this is one of many -- of numerous reasons which will be shown to overcome summary judgment. I mean, we have produced what relates to what he finally disclosed as what they want. They finally told us, "Here's what we want. Either put at least 440 milligrams of the drug in each vial or change the labeling." You can't do either one of those without FDA approval. End of claims. Now they want us to go -- they want to talk about what maybe should have been warranted instead of what's warranted. They want to talk -- a lawyer wants to tell what the FDA requires or doesn't require.

All we're asking for is if they're ready to oppose the motion, let's set a date and do it. If they want to take some depositions, let's take the depositions. If they have an expert that wants to sign an affidavit and says, "We need this to respond," then I think it would bring more clarity to where this discovery goes, because there doesn't seem to be any end

to what the plaintiffs want. There's never -- and I'm not looking for a pat on the back of what's been done, but the resources committed thus far have been significant in the gathering, the collection, the review, and then the identification of what might be out there from other sources as Your Honor had asked us to do.

So I just didn't -- I think if we're going to just accept conclusory assertions of a lawyer, then I don't think -- I don't think we're ever going to conclude this preemption discovery that Judge Kern had contemplated when he -- when back in June he ordered the initial preemption discovery.

And, Your Honor, they've had our disclosed expert since June 30th. We've served the declarations early, as Judge Kern had wanted, on August 9. Two weeks later we filed the summary judgment. So now, after two months of silence since the joint submission was submitted, we just get these global, broad, "Give us all the communications you have with the FDA, give us --" I mean, these requests couldn't be framed any broader, and --

THE COURT: Yeah. I mean, it occurs to me, you know, that one thing I could do, and I'm really half joking here, but one thing I could do is say, "Okay, look, just respond fully to every one of their requests," and then what you just said I think would be appropriate. But that's not what I've done. I've limited them so far on the correspondence for the FDA to

the issues involved in this specific case and I've told you all to get together and make sure that you take into account proportionality when you do that. I think in my discussion with Mr. Egli, I've been very clear that, you know, you need to find out how difficult this information is going to be to get. It sounds to me like in my discussion with him that there's going to be a way to limit it such that it's not overly burdensome on your client. And believe me, Mr. O'Connor, I appreciate your thoughts and your concerns. I've been on both sides of this issue before before I took the bench, so I understand.

One comment -- I mean, I think I've said this, you know, over and over again, and I do appreciate all the work Genentech has done, but I think I said at the outset of all this not to go gathering documents, but to just find out what it would take to gather the documents. And it appears to me, and I'll assume in an effort to be very cooperative you've actually gone and gathered documents, but that's not something I directed you to do. And so to the extent that you've incurred expenses doing that, that was, in large part, your own decision. Now, it probably will turn out that maybe that was all necessary anyway.

But I understand your concerns, Mr. O'Connor. I'm trying to take them into account and that's why I'm focusing on this proportionality. And again, you know, I'll say it again,

clearly Mr. Keglovits wants more than I'm giving him, and you all think -- believe he ought to get a lot less, and so, as I said in many ways, that tells me I'm probably in the right spot. So that's how we're going to handle the correspondence with the FDA on the labeling issue. And we can walk through the specific discovery requests later and see which ones that impacts, but I'm certain it narrows a number of them. It really wasn't my goal to get into the labeling issue then, but we took care of it.

All right. Let's go ahead and talk about the broader labeling issue, and that relates, I believe, to the obstacle preemption. And as I said at the beginning, my understanding was that -- I guess before I go on, let me make sure, Ms. Griffin, are you able to hear everyone now?

MS. GRIFFIN: Yes, we can hear. Tara Tabatabaie is on the phone, as well. But thank you for speaking into the mic, counsel.

THE COURT: All right. Well, I'm glad you said Ms. Tabatabaie -- did I say that right, the name -- because I was not going to get it right.

MS. TABATABAIE: You got very close.

THE COURT: Okay. So you all can hear. Good.

All right. So plaintiffs' discovery, the first area is the availability of labeling changes including discovery of information putting Genentech on notice of the fact that such

changes were necessary.

In terms of the information that I have just indicated is to be produced in discovery, Mr. Keglovits, what else do you think you would need? Is there anything else that would not be included?

MR. KEGLOVITS: Well, are you asking for me to point to our specific discovery requests?

THE COURT: Well, I mean, my intent is to walk through those later and then you all can tell me we've addressed it or we haven't addressed it.

MR. KEGLOVITS: Okay.

THE COURT: But I'm talking on this broader issue of the availability of labeling changes, including discovery. I mean, what are the factual underpinnings of that sort of category of documents?

MR. KEGLOVITS: Right. Well, I think there are two other areas that we haven't talked about that will be important to the labeling, and one of these area will overlay with manufacturing, too. The first is the internal Genentech e-mails and communications. As I mentioned before, we have zero Genentech-to-Genentech employee e-mails. Whether those deal with labeling or the myriad of manufacturing issues, we absolutely feel like we need to get into that.

And then the other area is going to include the customer or third-party communications that come to Genentech and the way

they formulate responses to them. As just a small example, you know, there was a letter written to the New England Journal of Medicine about this issue, about the fact that you were not getting what was warranted you were going to get, and that's, of course, my characterization of the article, and I've got it -- or the note -- if you'd like to see it.

Genentech formulated a response and wrote a letter to the New England Journal of Medicine about that. Well, surely that was more than someone who just typed it off the cuff and sent it off. I bet there was a group that worked on it, that researched it. We want to know all about that stuff. And we can also show you e-mails we have collected outside of the formal discovery where oncology practices are contacting Genentech and are being told, "This is a person who will respond to you," or "I can't respond to that; it's been routed to a different department in Genentech and they're going to respond to you." So, there was a process within Genentech that was created to deal with customers, distributors, whoever it is, saying, "We're getting shorted on the Herceptin. We don't understand why." And so we think that has to do with labeling, newly acquired information, and better information on the label, and we need that; we don't have those customer complaints or inquiries at all from Genentech. We fortunately have been able to get a few of them from sources, as I say, outside of Genentech. So those are the two principal areas

with respect to labeling.

THE COURT: All right. And then in your -- the joint submission, I think, in the reply near -- I'm trying to remember what issue it was under but I think it was near the end, you seem to -- well, you may this argument based on *Trayhan vs. Sandoz*, that you aren't arguing fraud on the FDA, in other words, that Genentech essentially fooled the FDA into approving a label that shouldn't have been approved, but you're saying that your position is that they should have requested a better label in the first place, essentially. I mean, have I summarized that correctly?

MR. KEGLOVITS: That portion dealing with the claim that we keep hearing that somehow we're bringing a fraud on the FDA claim, yeah.

THE COURT: Okay. So I want to talk about two things. First, on the labeling discovery, how is -- beyond what I've already addressed, how is this other labeling information directly responsive factually to the defendants' summary judgment motion?

MR. KEGLOVITS: Meaning the internal discussions about the --

THE COURT: Right.

MR. KEGLOVITS: -- label? I think the third-party complaints and the internal discussions with respect to just this labeling issue really goes to what we're trying to

accomplish on impossibility.

THE COURT: Okay. So you're back to -- okay. So your position is all this labeling stuff goes to the idea that it's not impossible because they could have changed the label. But I thought the linchpin or sort of the cog in the wheel there was that if the FDA said to change it, then they could change it. Are you also arguing that -- I mean, you think there might be some internal correspondence that indicates that Genentech, notwithstanding what the FDA said to them, could believe they could change it and therefore they could change it even if the FDA didn't ask them to? I mean, what's the --

MR. KEGLOVITS: Within the regulatory structure, there are these types of changes enumerated in the CFR that Genentech is allowed to make independent of approval from the FDA and they're divided into two groups. One is those that require a CBE, a simultaneous report that we have changed the label, and the other is you don't even have to do a simultaneous report, you can do an annual report at the end of the year just telling the FDA what you've changed.

And, again, part of the linchpin to the CBE stuff is newly acquired information. And if there is a belief that changing the label adds or strengthens an instruction about dosage and administration, then you can make that CBE type of change. So that's a separate exception from the one we're talking about -- we talked about earlier about the FDA requesting you make the

change. This is a separate one that you can make independent of the FDA.

And then on the annual report, I mean, you can make a change if you believe it's simply editorial or a minor change. So if you wanted to say it's not 21 is the concentration but it's some different fraction that's actually being reconstituted, and you believe that that's an editorial or minor change, someone writes that within Genentech, that's a pretty important piece on the labeling because that's going to push us right into an exception that would allow them to do it independently and destroy impossibility.

THE COURT: And, Ms. Donahue, your argument is that, look, it doesn't matter what -- it does not matter if they get an e-mail from a Genentech scientist saying we could do this, it's okay for us to do it or somebody in the regulatory department saying, "We can do this, we can make this change, we don't have to seek FDA approval, this is not a problem and we ought to just do it." I mean, let's say that smoking gun is out there for purposes of this argument. Your position on summary judgment is it doesn't matter; am I right about that?

MS. DONAHUE: Our position is, yes, under the approval letter and the regulation, that the regulation that does apply in this case, and it's not the CBE portion of the regulation, it's the portion that requires prior approval as borne out by the 2014 submission that they keep talking about. We have to

submit proposed changes for approval to the FDA. That's what that document shows.

THE COURT: Okay. Right, right, but let me --

MS. DONAHUE: So let me just finish. Sorry. I'm sorry. I'll get to your point. So my point would be that, two things. Number one, complaints about, "We're not getting, you know, the 440 from a customer, from anyone, or internal communications that Genentech somehow knew because it did that people were complaining about that," we've produced to them certificates of analysis XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX I mean, what they want goes to notice and knowledge, and I think to the extent that's an issue, which it's not under obstacle preemption, is what he just said, but, you know, they have that evidence. So what more do they need? I mean, we produced our own manufacturing documents XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

THE COURT: All right. Let me get back to -- I understand what you're saying, but let me get back to my question. Okay. So think of the worst document that could be in the files that Mr. Keglovits says he's looking for, and your position is, "I don't care how bad that document is, it doesn't matter, this is a legal issue and we win." I mean, am I right about that?

MS. DONAHUE: You're right about that for purposes of the motion for summary judgment.

THE COURT: Right. Right. Okay. So why don't we, on this issue, why don't you all -- Mr. Keglovits, I mean, I'm certain that you can, you've sort of done it here, that you can come up with the factual -- the facts that you believe the discovery you're seeking might show. I mean, am I right about that? I mean, you know -- you know what you're looking for. You know -- I would imagine if I asked you now and I gave you a little bit of time, you could say, "Okay, the golden egg, the smoking gun, the best we could hope for through this would be a document that says X." What I hear Ms. Donahue saying is, "I don't care. You can get 500 of those documents and we still win on the preemption argument."

So why don't you come up with a factual statement that Ms. Donahue can say, "We don't agree with this at all, but for purposes of ruling on our summary judgment motion we'll agree that there may be documents out there that say this. Judge Kern, make your decision." And if Judge Kern rules in their favor, then it doesn't matter what you would have found. And if he rules against them and says, "No, if there are documents out there that say this, then summary judgment on the preemption issue would not be appropriate," and then you all can -- I mean, the risk for Genentech on this, but I'm kind of asking that you put your money where your mouth is, is at that

point you would then have to proceed with merits discovery and the documentation that they're asking for may not even exist, and if you had allowed them to look, they might not have ever found it and so you would have resolved that whole issue, you know, right now. I mean, do you follow what I'm saying?

MS. DONAHUE: No. I do need you to repeat that.

THE COURT: Okay. So if you agree to submit to Judge Kern on this issue, or any number of these issues, essentially it's not a stipulation that you're agreeing this information is out there but essentially saying, "Look, our position is even if the documents that Mr. Keglovits hopes to find exist, even if they say A, B, C, D, which is what he is hoping they will say, we still win. This case is over, it's preempted, we're done." So, to avoid a lot of this discovery, certainly on this issue, Mr. Keglovits says, "Okay, these are the facts we are thinking we will find out there," and you say, "Fine, we'll agree that those facts -- that those facts might be out there but we win anyway," -- don't let me interrupt you two.

MS. DONAHUE: I'm sorry.

THE COURT: Okay. "So we believe that we win anyway even if those facts are out there." And then Judge Kern, in ruling on that, says one of two things, either, one, "Yeah, Ms. Donahue, I agree with you; even if Mr. Keglovits finds these documents, the claim is preempted, we're done." I mean, Mr. Keglovits, the case is over then and you haven't had to go

through all this discovery, you haven't spent all that money, and you've avoided a big hassle.

But if Judge Kern says, "No, wait. If there are documents out there that say what Mr. Keglovits says he thinks he's going to find, then either, one, it's not preempted, or, two, I'm going to have to take some other issues under consideration." If he does that, well then in my view you roll into discovery on the merits and you're just going to have to address that issue at some point later on down the road. I don't think Judge Kern is going to agree to a bifurcated summary judgment process by which we submit this issue and then we engage in preemption discovery and then we engage in merits discovery.

And so what I'm saying is if you're certain you're right about that, why not agree to go forward on, for purposes of preemption only, a stipulated set of facts that says, "We don't believe this stuff is out here, but even if it is we win, and if we don't win on that, well, then, we're going on to merits discovery and at some point down the road we'll file another summary judgment motion that will include preemption in there because we don't think they're going to find any of these documents." What I'm saying to you is that's a way to avoid a lot of this discovery right now, but what you could find out later on is, "Well, if we had only let them pursue this discovery, you know, prior to the preemption issue, well then we would have avoided all the merits discovery." I mean, does

that make sense?

MS. DONAHUE: Okay. I think I understand what you're saying now. So just to kind of be a little more specific, from a legal perspective on the obstacle preemption issue, our position is is that internal communications about potential labeling changes doesn't change the fact that the FDA approves the label as is and has been in effect for 20 years and, therefore, we win on obstacle preemption. That's our legal position on that issue. So -- and I would agree that therefore that's why our position is that they're not entitled and shouldn't be entitled to discovery because --

THE COURT: "Because it doesn't matter what they find," --

MS. DONAHUE: Yes.

THE COURT: -- "we win anyway."

MS. DONAHUE: However, when you phrase it as and then you're rolling the dice and taking a risk because if I don't allow them this discovery, this and this could happen, I mean, if that's how -- if you're going to couch your ruling on something like that, I would have to go talk to my client because --

THE COURT: Yeah.

MS. DONAHUE: -- they're going to have to make the decision.

THE COURT: Well, and here's what I'm thinking. I

think ultimately I probably have the authority just to do this, because I think Judge Kern would probably -- I think he would probably go along with it -- you know, Genentech is saying, "We don't need anymore discovery, we have everything we need, and no matter what the plaintiffs find, we still win. I mean, come up with your best set of documents, create them out of thin air, and we agree you're going to find those in spades with our company and we still win." I mean, that's essentially what Genentech is saying. Because if you're not saying that, then I think you have to knowledge that their discovery is relevant. "So, come up with those documents, you find them, we still win."

So, why not, rather than engage in, you know, a million, two million dollars worth of discovery here, why not have Mr. Keglovits say, "Factually, this is exactly what we believe we're going to find, and, in fact, we already have some of it," --

MR. KEGLOVITS: And --

THE COURT: -- and then go to Judge Kern in your response and say, "Judge Kern, they've agreed that for purposes of this motion alone this stuff may be out there, or maybe even is out there, but they win anyway, but for purposes of the rest of the case, they're in total disagreement that this stuff exists." And so the plaintiffs' position is, "If this stuff is out there, we avoid summary judgment."

MR. KEGLOVITS: That sounds wonderful in theory, and certainly we would be willing to try to work on the stipulation that would be satisfactory to us. I have to wonder, though, if Genentech really believes this motion involves only legal issues. If so, why are there two declarations attached to the motion that contained a group of factual statements?

THE COURT: Yeah. I mean, I think --

MR. KEGLOVITS: They would have to withdraw those.

THE COURT: Well, I mean, I hadn't thought all the way through that issue. I'm not certain I agree with that. I mean, we haven't talked about the manufacturing issue yet, and that is an issue that I think is -- that I just think is fraught with factual issues. But it just seems to me -- I mean, what I keep hearing from Genentech is, "This is a big waste of time. It doesn't matter what they find. We've given them everything they need, it doesn't matter what they find, we're still going to win on preemption."

And what I hear Mr. Keglovits saying is, "Look, we've already got these documents and we need to do this additional discovery because they've made a bunch of factual allegations in the summary judgment motion," and this, I believe, was Genentech's request to Judge Kern to deal with the preemption issue first.

So, I mean, what's the harm in -- I mean, I guess, Ms. Donahue, Mr. O'Connor, why am I not giving you everything

you want if, rather than doing any of this discovery, you sit down with Mr. Keglovits and he says, "Here are the facts I believe I can show if I get the discovery," and you all then agree, "Okay, for purposes of this motion, we'll agree you're going to find those facts, only for purposes of this motion. We're not agreeing that they're actually out there but we'll agree Judge Kern can assume that you might find -- that you'd find information that would support these factual allegations." And if you're right on your arguments, then Judge Kern is going to look at those factual stipulations -- or I don't even like to call them stipulations because they're only for purposes of this motion -- but he's going to look at that list and say, "That doesn't matter, Genentech, you win anyway, and so we're done."

MS. DONAHUE: So, two things, I think. First, I would want to see the factual list before agreeing to that. And, number two, I guess that would also assume that they are not going to introduce a declaration from an expert saying, "If I had this and this and this, I could respond to your motion." Because if it's a legal issue, it's a legal issue; right? I mean, our regulatory expert is interpreting the regs for the court. That's not raising a factual issue. But I'm just concerned about agreeing to -- you know, first of all, we don't think there are additional documents out there, so we don't want to go on record saying that, assuming there are.

But, number two, I really think in order to reach that agreement without seeing the facts that you're talking about would be doing something in a vacuum.

THE COURT: Well, I wouldn't ask anybody to do that today. I mean, it seems to me Mr. Keglovits would have to consult with whatever experts he's been talking to and come up with a list of -- and it seems to me it would also, if we can't reach an agreement, really narrow the issues on the discovery --

MS. DONAHUE: So --

THE COURT: -- because Mr. Keglovits would be saying, "These are the facts that I believe either we need to show or we'll be able to show if we get more discovery."

MS. DONAHUE: I think that's an expeditious way to handle the obstacle preemption issue, I really do, if we can, because you've got it right. If it's purely a legal issue and if they think that there's factual stuff that would help them overcome that legal issue, tell us what it is and then we'll decide if more discovery -- if we're amenable to more discovery or if we have to battle it all out. But at this point, as Mr. O'Connor kind of said, you know, we're kind of operating in a vacuum in terms of why they specifically need a whole bunch of stuff that goes to what we believe to be a legal issue.

THE COURT: Okay. So on the obstacle preemption issue, Mr. Keglovits, why don't we -- why wouldn't we want to

pursue it that way?

MR. KEGLOVITS: So -- and I'm just thinking out loud here -- the reg gives them coverage for reasonable variation in net weight if those are due to good distribution practice or by unavoidable deviations in good manufacturing practice, that's the reg that they hang their hat on. So we're talking about stipulating that these variations are not due to good distribution practice or unavoidable deviations?

THE COURT: No. What I'm thinking is come up with a list of factual statement, if you will, maybe something that -- well, with a factual statement, you know, "Here are the facts that we are trying to establish to beat your obstacle preemption defense, and we believe there are going to be documents that help us establish this," and then present that to Ms. Donahue and Mr. O'Connor. And if they're all factual statements, I don't think it's stipulating that, you know, with respect to a reg; it's purely factual issues, because that's what we're talking about here in discovery. Then they're going to have to look at that and say either, one, "Yeah, even if you establish all those facts, we still win on the obstacle preemption." And if the response is, "No, you know what, we can't agree that if you establish that fact we still win, and then we've got to have discovery on that issue."

But Mr. O'Connor and Ms. Donahue appear very confident that on the obstacle preemption issue, "This is purely a legal

issue, it doesn't matter what you find factually, we still win on this." And so then if they look at that list of facts and say, "Fine, even if we assume you can establish those facts, we still prevail on obstacle preemption, that's the nature of the agreement." It's not -- they're not agreeing that you can't establish those facts or that there are even any documents out there that address those facts. But it's simply, "Even if you can establish those, we win anyway." And then we avoid all discovery on the obstacle preemption and then all we've got to do is talk about the impossibility defense.

MR. KEGLOVITS: Yeah, I mean it sounds wonderful from our perspective, the plaintiffs' perspective, in theory. I just think we should put a very short window on this because I'm not optimistic we're going to be able to get them, for example, to stipulate that this is a liquid drug, not a solid drug.

THE COURT: Okay. Well, -- okay. Again, it's not a stipulation. It's --

MR. KEGLOVITS: Yeah.

THE COURT: It's if -- I mean, there's an example, if one of the things you think is going to help you avoid the obstacle preemption defense is factual proof that it is a liquid drug or a solid drug, if that's one of the factual issues you think would help you, then Ms. Donahue and Mr. O'Connor should be able to say, "Fine, we don't care.

Judge Kern can agree that you're going to be able to establish that and we still win on the obstacle preemption," and then move on to the next one. And if you hit a fact that really is a fact, and Ms. Donahue and Mr. O'Connor are saying, "No, we can't agree to that one," it seems to me we've now hit upon an issue upon which everybody has to agree discovery has got to be conducted. I mean, that's my thinking, and I wouldn't think it would be a long -- I mean, I'm talking about you guys ought to get together next week and figure this out.

MR. KEGLOVITS: Uh-huh.

THE COURT: Now, on the impossibility preemption, we have addressed the correspondence with the FDA. I mean, I guess one of my thoughts on this issue is -- and, Ms. Donahue, I guess I ought to hear from you on this. Looking through the summary judgment argument, and I've actually highlighted it, I could run through them all with you here but that probably won't be necessary, but in looking through your summary judgment motion and your affidavits, there are a lot of allegations about what can and cannot be done in the manufacturing process, and those to me seem to be factual issues.

In other words, in the manufacturing process that Genentech uses and has used, is it a correct statement that in order to make sure you get at least 400 milligrams, you're going to have to bump up the upper level? I mean, that's a factual issue,

which means that the plaintiffs are going to need to delve into in probably quite a bit of detail the manufacturing process.

So, one thing that occurs to me is that if you all are able to reach an agreement on how we proceed on the obstacle preemption, understanding that there's going to be a lot of discovery on the impossibility preemption issue, why not present the obstacle preemption issue to Judge Kern, and then if you don't prevail on that, then we just proceed with discovery on both the merits and the impossibility preemption because it's going to be a lot of discovery anyway.

MS. DONAHUE: Short of conferring with my client, that sounds like a good idea.

THE COURT: Mr. Keglovits?

MR. KEGLOVITS: Well, I want to talk to my colleagues. But I'll be honest with you, we embarked on this -- and there I did it, I said I'll be honest with you --

THE COURT: I actually -- I know, Ms. Donahue, I gave you a hard time about that, but I actually said that in a hearing last week, and I caught myself, and so I was giving you a hard time.

MS. DONAHUE: Thank you.

MR. KEGLOVITS: I'll be completely candid with you --

THE COURT: Okay.

MR. KEGLOVITS: -- and not hold anything back. We started down this road in early June thinking that it would end

quickly, and the process now has, as you're describing, now even pushes us further out, and so --

THE COURT: See, I don't think it does. I actually think it gets you there quicker, because if we -- if I give you the discovery that you're asking for on the impossibility defense, and it's going to be quite a bit of discovery, you go through that process, then you file your response to the summary judgment motion, which I can't imagine will be within 90 days, I mean maybe, but I can't imagine that you're going to get through this that quickly, and then Judge Kern rules, and then if you win, if you avoid the summary judgment, then we go to merits discovery, and I know you guys are going to agree on everything once we get to the merits, and so, you know, we're way out there before we ever get to merits.

If you do it this way, you get -- it's sort of -- it's a nice compromise because you get the obstacle preemption issue decided, and if Judge Kern does not rule in favor -- if Judge Kern rules in favor of Genentech, the case is over anyway. And if he doesn't, then you engage on full discovery, impossibility defense and the merits.

MR. KEGLOVITS: Okay.

THE COURT: And so to me that gets you down the road a lot more quickly than you would be otherwise.

MR. KEGLOVITS: I misunderstood. I thought we were going to do obstacle and then --

THE COURT: No.

MR. KEGLOVITS: -- if we win on that then we have to go to impossibility.

THE COURT: No.

MR. KEGLOVITS: Okay. Well, if you would, just give us a moment, as they confer with their client, to think about it internally and see if that's acceptable to us.

THE COURT: Yeah. I mean, do you guys want to talk about it, take a break and talk about it now, or do you want to go back and talk to your client? I mean, what do you want to do?

MS. DONAHUE: I think I probably need a day.

THE COURT: Okay. So --

MR. KEGLOVITS: A day is fine, yeah.

THE COURT: Okay. All right. Then let's -- okay. It's Thursday. What's our schedule Monday?

(A DISCUSSION WAS HAD OFF THE RECORD, AFTER WHICH THE FOLLOWING PROCEEDINGS WERE HAD:)

MS. DONAHUE: We could do it tomorrow, Your Honor, if that's helpful.

THE COURT: I'm thinking about doing it by phone. So, Mr. Keglovits, would tomorrow work?

MR. KEGLOVITS: Let me get my calendar to work here. And I hate to impose, but if we could just do it outside of the 2 to 3 window, when I've got another obligation, tomorrow would

work for me.

THE COURT: How about if we do it at -- I mean, would 4 o'clock tomorrow work? Is that too late?

MS. DONAHUE: I just have to check my flight schedule. I'm sorry.

THE COURT: Yeah, take a look.

What you're hearing is me trying to avoid the black robe syndrome. I ask Camie, "When should we do this," and her response is always, "Whenever you want to do it." And so then we argue about whether that ought to be her response.

MS. DONAHUE: I'm sorry. What time are you saying?

THE COURT: At 4 tomorrow.

MS. DONAHUE: I'm on a flight.

THE COURT: Okay. What are your flights?

MS. DONAHUE: So my flight leaves here at 11.

THE COURT: Does it give you a long enough time if we do it late morning?

MS. DONAHUE: I can call this afternoon, I'm sure.

THE COURT: Okay.

(A DISCUSSION WAS HAD OFF THE RECORD, AFTER WHICH THE FOLLOWING PROCEEDINGS WERE HAD:)

THE COURT: Why don't we do it at 10:30 tomorrow morning? Does that give everybody enough time? Okay.

MR. O'CONNOR: You leave at 11?

MS. DONAHUE: Yeah. Well, I'll be in the airport, if

you don't mind airports.

THE COURT: I'm fine, as long as you're okay with that.

MS. DONAHUE: It will be a quick call. I mean, it's just a yea or nay.

THE COURT: Yeah. All right. Just, you know, so everything is transparent, I'm going to talk to Judge Kern about this. I think he'll be fine with it. So you'll know, the risk you always run, he may just say, "I like that and that's how we're going to do it." But I think he'll probably take your input, as will I, tomorrow. So, tomorrow morning, 10:30. Can somebody set up a call-in number? That might be the best way to do it.

MR. O'CONNOR: We can.

MS. DONAHUE: We can do that.

THE COURT: Okay. I guess Mr. O'Connor will set up a call-in number and so then we'll talk tomorrow morning at 10:30.

MR. KEGLOVITS: And, Your Honor, if we happen to talk between then and now and agree on it, should we just call you and let you know that --

THE COURT: All right. That would be great. That would be great.

MR. KEGLOVITS: -- to save you the trouble of --

THE COURT: Yeah.

MR. KEGLOVITS: -- of everybody getting together?

THE COURT: That would be great. And then if you do that, then call with a deadline for you all to get back to me on the factual -- the agreement -- kind of the basis of the agreement that would allow you to go forward on the obstacle preemption.

MR. KEGLOVITS: Okay.

THE COURT: And then we would just enter a minute order.

MR. KEGLOVITS: So, to make sure I'm clear, I'm supposed to say whether we'll agree to go forward on obstacle only, and we are going to work on whatever -- and I'm using the word "stipulation" because I don't know what the right word is, but --

THE COURT: Yeah.

MR. KEGLOVITS: -- but I understand it's not a stipulation, what set of facts we would agree to for purposes of that motion --

THE COURT: Right.

MR. KEGLOVITS: -- to keep us from doing any discovery?

THE COURT: Right. And the nature of Genentech's agreement would simply be, "Even if they were to establish this, it doesn't matter," and that's kind of a crude way of saying it, but --

MS. DONAHUE: However, if we say, "Well, yeah, maybe we do need to do some discovery on obstacle preemption," I mean, we're still operating within that, let's just go with obstacle first, and then --

THE COURT: I mean, if you decide you need to do that, you all talk. I mean, it's going to be -- then I'm going to begin weighing how long will that take, what sort of discovery is it, and does it make sense to then just go ahead and pursue the impossibility, as well.

MS. DONAHUE: Okay. And then one other point that I want to make sure I understand. I would assume that for Judge Kern, if they provide an expert declaration that said, "If I only had this and this and this, had been able to assess it, not necessarily whether it proves one thing or another, I would have been able to" -- I mean, I'm just a little worried that there's -- you know, that would be something that we would be entitled to I think under Rule 56, you know, in order for us to respond to that. So I'm just a little nervous about that, if these factual issues --

THE COURT: If you all -- I mean, my view is if you all come to an agreement on the factual issues -- I mean, they may have an expert report but that expert's going to have to assume that those factual issues are established. I mean, that would be --

MS. DONAHUE: Okay.

THE COURT: -- the nature of it because you all are saying --

MS. DONAHUE: So it's not -- the expert's going to have to assume the facts were established, not say, "Because I didn't get a chance to look at this," whatever --

THE COURT: Right, right.

MS. DONAHUE: -- it might be, you know.

THE COURT: I mean, I would think that would be the nature, is Mr. Keglovits can go to his expert and say, "For purposes of this motion, we're assuming that I can show these facts."

MS. DONAHUE: Okay. That's -- yeah.

THE COURT: I mean, and I know there's some details you guys are going to have to work out, --

MR. KEGLOVITS: It's tremendously difficult when they've got an expert who is saying, "Based on the facts as I learned them when I used to work at the FDA, this is a solid drug, not a liquid drug."

THE COURT: And I understand that, but I mean I really view this, one, Ms. Donahue and Mr. O'Connor have made it very clear on obstacle preemption, "It doesn't matter what the facts are, we win." Okay. So that should give a lot of leeway to the plaintiffs in coming up with whatever facts they want.

And then on the plaintiffs' side, you all -- and I'm not saying you haven't done this -- in pursuing your discovery,

you've got to be able to articulate the facts you want to be able to show, because if you're not, then how do I give you discovery? So those facts would be the ones that you would be showing an expert anyway and that's what the expert would then be opining on.

So, with that, you all get together, we'll talk tomorrow at 10:30, if I don't hear from you beforehand. If you both agree to go forward this way, then we'll have a short period of time for you all to get together the factual issues and then I'll just set another conference call to get an update on that. If you all reach an agreement, then the same thing on all of this, you can contact Camie and say, "We're good."

MR. KEGLOVITS: Okay.

THE COURT: Okay?

MS. DONAHUE: Good.

One last question. How does this affect the original or your initial order on the correspondence?

THE COURT: No, no. That's --

MS. DONAHUE: Gone?

THE COURT: If you reach an agreement on this, then there won't be any further discovery until --

MS. DONAHUE: Okay. Thank you, Your Honor.

THE COURT: Okay. All right. So, Mr. Keglovits, anything else?

MR. KEGLOVITS: No, Your Honor.

THE COURT: Okay. Ms. Donahue?

MS. DONAHUE: No, Your Honor.

THE COURT: Okay. And I'll sign the ESI orders. Thanks for your time.

MS. DONAHUE: Thank you.

MR. KEGLOVITS: Thank you.

THE DEPUTY COURT CLERK: All rise.

(PROCEEDINGS CLOSED)

REPORTER'S CERTIFICATION

WHILE NOT PRESENT IN PERSON TO STENOGRAPHICALLY REPORT THE FOREGOING PROCEEDINGS, I CERTIFY THAT IT WAS TRANSCRIBED TO THE BEST OF MY ABILITY FROM A DIGITAL AUDIO RECORDING.

CERTIFIED: *s/Greg Bloxom*

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